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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,368	06/28/2001	David M. Allen	P1067	2222

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EXAMINER

DEWITTY, ROBERT M

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 11/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/896,368

Applicant(s)

ALLEN, DAVID M.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-23 are pending in the instant application.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, 6-11, 14-19, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Crandall (U.S. Pat. No. 5,560,910).

Crandall relates to compositions and methods useful for topically treating inflammation. The anti-inflammatory compositions contain a proteolytic enzyme, and a pharmaceutically effective penetrating agent (col. 1, lines 59-67). Suitable penetrating agents include lecithin organogel (col. 2, line 1). Regarding the use of penetrating agents, Crandall teaches that current use of NSAIDs for treatment of diseases, such as arthritis, are ineffective because only a therapeutically ineffective amount of drugs can penetrate the skin (col. 1, lines 13-21). Crandall further teaches that the composition can include antibacterial, antifungal, antiprotozoal, or antiviral agents (col. 2, lines 25-33). At Example 1, the use of Pluronic Gel and Lecithin organogel in the composition are taught (col. 5 at Example 1).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crandall further in view of Gupta (U.S. Pat. No. 6,281,199), and current knowledge in the art.

As stated above, Crandall relates to compositions and methods useful for topically treating inflammation. Penetrating agents are contained in the compositions. Suitable penetrating agents include lecithin organogel (col. 2, line 1). Crandall further teaches that the composition can include antibacterial, antifungal, antiprotozoal, or antiviral agents (col. 2, lines 25-33). At Example 1, the use of Pluronic Gel and Lecithin organogel in the composition are taught (col. 5 at Example 1). Crandall, however, does not teach the use of azithromycin, erythromycin, or roxithromycin.

Gupta relates to a method for applying an antibiotic to address inflammation in the blood of patients. The preferred antibiotic is azithromycin, and it is taught by Gupta that application of the antibiotic may lead to a reduction of inflammation possibly through eradication of underlying *Chlamydia pneumoniae* infection (col. 1, line 65-col. 2, line 4).

As it is known in the art that *Chlamydia* is believed to be responsible for musculoskeletal disease (instant specification page 6), the use of azithromycin and a penetrating agent for topically treating inflammation would have been known to one with

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ordinary skill in the art. Motivation to use a penetrating agent with azithromycin would have arisen in order to allow a therapeutically effective amount of azithromycin to reach the Chlamydia infection, which is likely the cause of the inflammation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Michael DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD  
November 9, 2001



NEIL S. LEVY  
PRIMARY EXAMINER

NEIL S. LEVY  
PRIMARY EXAMINER